

## REMARKS

Reconsideration of the subject application is respectfully requested.

Claims 1-7, 9-12 and 17-19 were pending as of the Office Action mailing date of October 13, 2010. This Reply is timely filed within the three (3) month time period for reply set forth in the Action.

### **I. REJECTION OF CLAIMS 1-7, 9-12, and 17-19 UNDER 35 USC 103(a).**

Claims 1-7, 9-12, and 17-19 have been rejected under 35 USC 103(a) as being unpatentable over US Pat. Application Pub. No. 2003/0207326 to Sue in view of U.S. Pat. No. 6,875,671 to Faris.

Applicant respectfully traverses this rejection.

The current invention, as now claimed, requires, inter alia:

a biologically effective layer configured to host at least one of a non-lipid molecule and a biologically functional molecule (amended claim 1, emphasis added)

Support for this amendment is found in the specification as filed, page 6, lines 19-23. As understood and disclosed in the specification of the subject application, a biologically functional molecule is one that retains full biological functionality.

The claim, as now presented requires the molecule in the layer to be biologically functional.

Applicant acknowledges that the current rejection is based on the combined teachings of the two cited references of record. Applicant will proceed by providing distinctions of each reference individually followed by distinctions of the combined references as a single disclosure.

As will be set forth below, the cited Su reference is deficient for failing at least to teach the claimed biologically functional molecule.

Su discloses a nanopore structure where an electric field is applied in order to transport labeled or marked proteins through ion channels generated by single ion channels in lipid bilayer membranes. Such ion channels may include, but are not limited to, *Staphylococcus aureus* alpha-hemolysin and/or mitochondrial voltage-dependent anion channels. The electric field applied to proteins can cause these molecules to move through the ion channels in the lipid bilayer membranes. Ion channels may be incorporated into chips and operably coupled to detectors. Therefore, Su requires the disclosed nanopore structure with ion channels for the identification and the sequencing of proteins, which are for this purpose first marked and then conveyed through the ion channel installed in the nanopores by the electric field (Su, paragraph [0072]).

The lipid bilayer as claimed in claim 1 of the subject invention does not have ion channels installed in the nanopores because the structure claimed in the subject invention is formed to characterize proteins that are in-vivo built-in into the lipid bilayer. The subject invention **does not** transport these proteins through the nanopores in terms of "tearing them through" the channels by means of an electric field as is known in the art and taught by Su.

The entire impetus of the Su invention is to use labeled molecules, as evidenced by repeated disclosure at least in paragraphs, [0016, 0017, 0021, 0053, 0080, 0092], and published claims 1-16, and 27-30.

Additionally, in order to use a reference as prior art, the MPEP 2141.02 and applicable case law provide "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)

The use of labeled molecules is contrary to the claimed invention which neither desires nor requires any type of labeling or marking.

The lipid bilayer as claimed in the subject application does not require to mark the proteins and to observe their movement through the membrane, but to quantitatively investigate whether a distinct protein incorporated into the lipid bilayer

(attached, fixed to the lipid bilayer) allow the lipid-bound proteins to move through the lipid bilayer and allow other proteins to pass through the lipid bilayer resp. Su only uses an electric field to convey proteins, peptides and amino-acids through the ion-channels that are installed in the lipid bilayer and the structure disclosed and described in Su is incapable of verifying whether a protein to be investigated has the ability to amend the characteristics of the lipid bilayer in a way that other proteins are enabled to pass through the lipid bilayer or to get attached to the lipid bilayer and allow other molecules to take advantage from these amendments made to the lipid bilayer on either or both sides of the lipid bilayer.

The structure disclosed and described by Su does not teach or suggest in any manner, the preparation of the claimed lipid bilayer that has a structure suitable to study the material transport phenomena without having ion channels installed in the nanopores and tearing proteins by an electric field applied through the ion channels.

The lipid bilayer of the present invention is used to cover the nanopores with a "living structure" showing a biological functional behaviour as under in-vivo circumstances that would be for proteins to be investigated for their biological/pharmaceutical behaviour.

Su is cited in combination with Faris in order to assert an obviousness rejection over the subject invention.

Faris is cited to teach a structure having alignment markings.

Combining the disclosure of Su and Faris into a single instructive disclosure would provide the skilled artisan with an invention that is a nanopore structure, formed with alignment markings, where an electric field is applied in the structure in order to transport labeled or marked proteins through ion channels generated by single ion channels in lipid bilayer membranes.

This combined disclosure remains deficient because the combined teaching does not provide any teaching or suggestion whereby the structure is formed with the claimed biologically effective layer configured to host at least one of a non-lipid molecule and a biologically functional molecule. The combined disclosure of Su and Faris requires ion channels installed in nanopores and tearing proteins by an electric field applied through the ion channels that is undesired and very different from the structure of the present invention.

Because the combined Su and Faris references are deficient for failing to teach, suggest, or provide any motivation to modify in order to arrive at the claimed biologically effective layer, Applicant asserts a rejection under 35 USC 103(a) cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

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Reply to Office action of 10/13/2010

Please charge any fees that might be due with respect to Sections 1.16 and 1.17 to  
Deposit Account Number 12-1099 of Lerner Greenberg Sterner LLP.

Respectfully submitted,

/Laurence A. Greenberg/  
Laurence A. Greenberg  
Reg. No. 29308

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Lerner Greenberg Sterner LLP  
P.O. Box 2480  
Hollywood, Florida 33022-2480  
Tel.: (954) 925-1100  
Fax: (954) 925-1101

DWB/bb